

WHAT IS CLAIMED IS:

1. A method for manufacturing an implantable medical device having a surface adapted for exposure to body tissue of a patient, wherein at least a portion of the surface is
5 covered with a coating having a desired amount of a biologically active material, said method comprising:

- (a) providing a first medical device having a surface;
- (b) applying to a portion of the surface of the first medical device a coating
10 composition comprising the biologically active material in a manner such that a coating containing an amount of the biologically active material in excess of the desired amount of biologically active material is formed on the surface of the first medical device;
- (c) determining the amount of biologically active material in the coating that is
15 in excess of the desired amount of biologically active material; and
- (d) ablating a portion of the coating containing the amount of biologically active material in excess of the desired amount using an ultraviolet (UV) laser.

20 2. The method of claim 1, wherein the ultraviolet laser has pulse length shorter than about 100 nanoseconds and a repetition rate less than about 100 Hertz.

25 3. The method of claim 1, wherein the step (c) is conducted by weighing the first medical device before and after application of the coating composition on the surface of the first medical device.

30 4. The method of claim 1 wherein the surface of the first medical device is curved.

35 5. The method of claim 1 wherein only the coating but not the first medical device is ablated.

6. The method of claim 1 wherein the coating comprises more than one layer, and the ablating step (d) is conducted on only the outermost layer of the coating.

7. The method of claim 1, wherein the steps (c) and (d) are repeated as necessary until the coating contains the desired amount of biologically active material.

8. The method of claim 1 wherein, before the coating is ablated, the thickness of the coating is estimated by:

10 (i) applying to at least a portion of a surface of a second implantable medical device the coating composition, in substantially the same amount and same manner that was used to form the coating on the surface of the first medical device, to form a coating on the surface of the second medical device, wherein the first and second medical devices are 15 made of the same material and have substantially the same configurations and dimensions;

20 (ii) ablating a portion of the coating of the second medical device with the ultraviolet (UV)-laser to expose a portion of the surface of the second medical device and to create a step having a height in the coating;

(iii) determining the thickness of the coating of the second medical device by measuring the height of the step using a white light interferometer; and

(iv) estimating the measured thickness of the coating of the first medical device 25 based on the thickness of the coating of the second medical device.

9. The method of claim 8 which further comprises repeating steps (ii) and (iii) using a different portion of the coating of the second medical device and wherein an average 30 of the measured thicknesses of the coating of the second medical device is obtained and wherein the thickness of the coating of the first medical device is estimated based upon the average.

10. The method of claim 8 which further comprises conducting steps (i), (ii) and (iii) using at least one additional implantable medical device; and wherein an average of the measured thickness of the coating of the second medical device and the measured thicknesses of the coating of the additional medical device(s) is obtained; and wherein the 5 thickness of the coating of the first medical device is estimated based upon the average.

11. The method of claim 1 wherein the laser has a wavelength between about 157 nm and about 193 nm.

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12. The method of claim 1 wherein the coating composition comprises a polymeric material which is selected from the group consisting of poly-L-lactic acid, polycarbonate, polyethylene terephthalate, silicones, polyurethanes, thermoplastic elastomers, 15 ethylene vinyl acetate copolymers, polyolefin elastomers, hydrogels and ethylene-propylene-diene (EPDM) rubbers.

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13. A method for manufacturing an implantable medical device having a surface adapted for exposure to body tissue of a patient, wherein at least a portion of the surface is covered with a coating having at least two layers, and wherein the coating comprises a biologically active material, said method comprising:

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(a) applying to at least a portion of a surface of a first implantable medical device a first coating composition to form a first layer of the coating;

(b) applying to the first layer of the first medical device a second coating composition to form a second layer of the coating thereon; and

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(c) ablating a portion of the second coating layer using an ultraviolet (UV) laser.

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14. The method of claim 13, wherein the ultraviolet laser has a pulse length shorter than about 100 nanoseconds and a repetition rate less than about 100 Hertz.

15. The method of claim 13 wherein the surface of the first medical device is curved.

16. The method of claim 13 wherein the portion of the second layer is ablated in
5 a manner such that the first layer is substantially not ablated.

17. The method of claim 13 wherein at least one of the first layer and the second
layer comprises a biologically active material.

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18. The method of claim 13 wherein at least one of the first coating composition
and the second coating composition is substantially free of a biologically active material.

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19. The method of claim 13, wherein the medical device is a stent comprising a
first end, a second end and a middle section and wherein the portion of the second layer that
is ablated is located at the middle section of the stent.

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20. The method of claim 19 wherein the first layer and the second layer both
comprise a biologically active material and wherein the concentration of the biologically
active material in the first layer is less than the concentration of the biologically active
25 material in the second layer.

21. The method of claim 13 which further comprises estimating the thickness of
the second layer of the first medical device.

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22. The method of claim 21 wherein the thickness of the second layer of the first
medical device, is estimated by:

35 (i) applying to at least a portion of a surface of a second implantable medical
device and a surface of a third implantable medical device the first coating composition, in

substantially the same quantity and manner that was used in applying the first coating composition to the surface of the first medical device, to form first layers on the surfaces of the second and third medical devices, wherein the first, second and third medical devices are made of the same material and have substantially the same configurations and

5 dimensions;

(ii) ablating a portion of the first layer of the second medical device with an ultraviolet (UV) laser, having a pulse length shorter than about 100 nanoseconds and a repetition rate less than about 100 Hertz, to expose a portion of the surface of the second

10 medical device and to create a first step having a height in the first layer;

(iii) determining the thickness of the first layer of the second medical device by measuring the height of the first step obtained in step (ii) using a white light interferometer;

15 (iv) applying to the first layer of the third medical device the second coating composition, in substantially the same quantity and manner that was used in applying the second coating composition to the first layer of the first medical device, to form a second layer on the third medical device;

20 (v) ablating a portion of the first and second layers of the third medical device with an ultraviolet (UV) laser, having a pulse length shorter than about 100 nanoseconds and a repetition rate less than about 100 Hertz, to expose a portion of the surface of the third medical device and to create a second step having a height in the first and second layers;

25 (vi) determining the total thickness of the first and second layers of the third medical device by measuring the height of the second step obtained in step (v) by using a white light interferometer; and

(vii) estimating the thickness of the second layer of the first medical device based

30 upon the difference between the total thickness obtained in step (vi) and the thickness of the first layer obtained in step (iii).

35 23. The method of claim 22 which further comprises repeating steps (ii) and (iii) using a different portion of the first layer of the second medical device and obtaining an

average of the measured thicknesses of the first layer of the second medical device and wherein the average is used to estimate the thickness of the second coating layer of the first medical device in step (vii).

5 24. The method of claim 22 which further comprises conducting steps (i), (ii) and (iii) using at least one additional medical device; and obtaining an average of the measured thickness of the first layer of the second medical device and the measured thickness of the first layer of the additional medical device(s); and wherein the average is
10 used to estimate the thickness of the second layer of the first medical device in step (vii).

15 25. The method of claim 22 which further comprises repeating steps (v) and (vi) using a different portion of the first and second layers of the third medical device and obtaining an average of the measured total thicknesses of the first and second layers of the
third medical device and wherein the average is used to estimate the thickness of the second layer of the first medical device in step (vii).

20 26. The method of claim 22 which further comprises conducting steps (iv), (v) and (vi) using at least one additional medical device; and obtaining an average of the measured total thickness of the first and second layers of the second medical device and the measured total thickness of the first and second layers of the additional medical device(s) is
25 obtained; and wherein the average is used to estimate the thickness of the second layer of the first medical device in step (vii).

30 27. The method of claim 13 wherein the first coating composition comprises a polymeric material selected from the group consisting of poly-L-lactic acid, polycarbonate, polyethylene terephthalate, silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, hydrogels and ethylene-propylene-diene (EPDM)
35 rubbers.

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28. The method of claim 13 wherein at least either the first layer or the second layer comprises a biologically active material.

29. A method for measuring a thickness of a coating applied to at least a portion 5 of a surface of an implantable medical device comprising:

(a) ablating a portion of the coating with an ultraviolet (UV) laser having pulse length shorter than about 100 nanoseconds and a repetition rate less than about 100 Hertz to expose a portion of the surface of the medical device and to create a step having a height in 10 the coating; and

(b) determining the thickness of the coating by measuring the height of the step by using a white light interferometer.

15 30. The method of claim 29 which further comprises repeating steps (a) and (b) using a different portion of the coating and wherein an average of the measured thickness of the coating is obtained.

20 31. A method for manufacturing a medical device having a surface adapted for exposure to body tissue of a patient, wherein the surface has a plurality of openings therein, and wherein at least a portion of the surface is covered with a coating in a manner such that 25 the openings are substantially free of coating, said method comprising:

(a) applying a coating composition to the surface of the medical device to form a coating thereon; and

(b) using an ultraviolet (UV) laser having pulse length shorter than about 100 30 nanoseconds and a repetition rate less than about 100 Hertz to ablate coating present in the openings of the surface.

35 32. The method of claim 31 wherein the coating composition comprises a biologically active material.

33. A device manufactured according to the method of claim 31.

34. The method of claim 31 wherein the ultraviolet (UV) laser has a wavelength
5 between about 157 nm and about 193 nm.

35. A method for manufacturing an expandable stent having a surface adapted
for exposure to body tissue of a patient, and wherein at least a portion of the surface of the
10 stent comprises a plurality of struts and wherein the struts are covered with a coating
substantially free of cracks, said method comprising:

15 (a) applying a coating composition to at least one of the struts to form a coating
thereon; and
(b) using an ultraviolet (UV) laser, having pulse length shorter than about 100
nanoseconds and a repetition rate less than about 100 Hertz, to remove a portion of the
coating on the strut to prevent the coating from cracking.

20 36. The method of claim 35 wherein at least one of the struts comprises at least
one bend and wherein the portion of the coating on the strut that is removed is located at the
bend.

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